



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,947	11/26/2003	Jorge Dubcovsky	514112000320	4243
20872 7590 06/15/2007 MORRISON & FOERSTER LLP 425 MARKET STREET SAN FRANCISCO, CA 94105-2482			EXAMINER BAUM, STUART F	
			ART UNIT 1638	PAPER NUMBER
			MAIL DATE 06/15/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/723,947	Applicant(s) DUBCOVSKY ET AL.	
	Examiner Stuart F. Baum	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23, 38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 38 and 39 is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RCE Acknowledgment

1. The request filed on 3/26/2007 for a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114, based on parent Application No. 10/723,947 is acceptable and a RCE has been established. An action on the RCE follows.
2. Claims 1-23 and 38-39 are pending.
Claims 24-37 have been canceled.
Claims 38-39 have been newly added and are drawn to the elected invention.
3. Claims 1-23 and 38-39, including SEQ ID NO:75 and 79 are examined in the present office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 23 is indefinite in the recitation "the nucleic acid". There is no antecedence for said recitation or Applicants have not defined "the nucleic acid".

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to an isolated nucleic acid comprising a sequence having at least 95% identity to SEQ ID NO:75; or wherein the isolated nucleic acid is operably linked to a promoter, or a vector, cell, or transgenic plant comprising said nucleic acid.

Applicants disclose that in a previous study, the wheat vernalization gene VRN2 was mapped to the long arm of chromosome 5A using a segregating population from the cross between *Triticum monococcum* DV92 (*vrn1vrn2*, spring) and G3116 (*vrn1Vrn2*, winter) (page 70, 2nd full paragraph). Applicants cloned the VRN2 gene and renamed it as ZCCT1 whose sequence is set forth in SEQ ID NO:75 (page 24, 2nd full paragraph; page 12, and sequence listing). Applicants disclose the name, ZCCT1, is based on the presence of a putative zinc finger in the first exon and a CCT domain in the second exon. The CCT domain was named after CO, CO-like, and TOC1 (page 73, 3rd full paragraph). Applicants disclose the name "VRN" is not the VRN gene from Arabidopsis (page 47, 4th paragraph). In the Remarks filed 3/26/2007, Applicants present an alignment between SEQ ID NO:75 and SEQ ID NO:79.

Art Unit: 1638

Applicants disclose the two sequences share 95.6% identity with each other (page 6 of Remarks, 2nd paragraph).

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

The Applicants do not disclose a correlation between function and structure, i.e., they do not include a functional limitation in claim 1 to go along with the 95% identity to SEQ ID NO:75. Applicants have not disclosed that a sequence exhibiting 95% identity with SEQ ID NO:75 will have the same activity as the protein encoded by SEQ ID NO:75. In addition, Applicants have not disclosed if SEQ ID NO:79 encodes a protein with the same activity as the protein encoded by SEQ ID NO:75.

Enablement

6. Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed invention is not supported by an enabling disclosure taking into account the *Wands* factors. *In re Wands*, 858/F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988). *In re Wands* lists a number of factors for determining whether or not undue experimentation would be required by one skilled in the art to make and/or use the invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claim.

The claims are drawn to an isolated nucleic acid comprising a sequence having at least 95% identity to SEQ ID NO:75; or wherein the isolated nucleic acid is operably linked to a promoter, or a vector, cell, or transgenic plant comprising said nucleic acid.

Applicants disclose that in a previous study, the wheat vernalization gene VRN2 was mapped to the long arm of chromosome 5A using a segregating population from the cross between *Triticum monococcum* DV92 (*vrn1vrn2*, spring) and G3116 (*vrn1Vrn2*, winter) (page 70, 2nd full paragraph). Applicants cloned the VRN2 gene and renamed it as ZCCT1 whose sequence is set forth in SEQ ID NO:75 (page 24, 2nd full paragraph; page 12, and sequence listing). Applicants disclose the name, ZCCT1, is based on the presence of a putative zinc

Art Unit: 1638

finger in the first exon and a CCT domain in the second exon. The CCT domain was named after CO, CO-like, and TOC1 (page 73, 3rd full paragraph). Applicants disclose the name "VRN" is not the VRN gene from Arabidopsis (page 47, 4th paragraph). In the Remarks filed 3/26/2007, Applicants present an alignment between SEQ ID NO:75 and SEQ ID NO:79. Applicants disclose the two sequences share 95.6% identity with each other (page 6 of Remarks, 2nd paragraph).

The state-of-the-art is such that one of skill in the art cannot predict which nucleic acids that exhibit 95% identity to SEQ ID NO:75 will encoded a protein with the same activity as the protein encoded by SEQ ID NO:75. The prediction of protein structure from sequence data and, in turn, utilizing predicted structural determinations to ascertain functional aspects of the protein, is extremely complex, and the positions within the protein's sequence where amino acid substitutions can be made with a reasonable expectation of maintaining function are limited (Bowie et al, Science 247:1306-1310, 1990, see especially page 1306). Proteins may be sensitive to alterations in even a single amino acid in a sequence. For example, the replacement of a glycine residue located within the START domain of either the PHABULOSA or PHAVOLUTA protein receptor with either an alanine or aspartic acid residue, alters the sterol/lipid binding domain (McConnell et al, Nature 411 (6838):709-713, 2001, see especially page 710, left column, 2nd paragraph).

In the absence of guidance, undue trial and error experimentation would be required for one of ordinary skill in the art to screen through the multitude of non-exemplified sequences, either by using non-disclosed fragments of SEQ ID NO:75 as probes or by designing primers to undisclosed regions of SEQ ID NO:75 and isolating or amplifying fragments, subcloning the

Art Unit: 1638

fragments, producing expression vectors and transforming plants therewith, in order to identify those, if any, that encode a protein with the same activity as the protein encoded by SEQ ID NO:75, whose activity Applicants have not specified.

Therefore, given the breadth of the claims; the lack of guidance and examples; the unpredictability in the art; and the state-of-the-art as discussed above, undue experimentation would be required to practice the claimed invention, and therefore the invention is not enabled.

7. Claims 1-23 and 38-39 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:75 or 79, or an isolated nucleic acid comprising a sequence having at least 95% identity to SEQ ID NO:75; vector, cell, and transgenic plant comprising said nucleic acid.

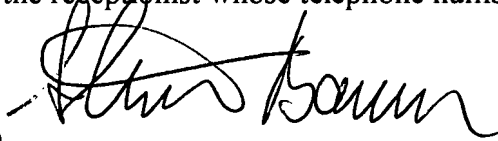
8. Claims 38-39 are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1638

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

A handwritten signature in black ink, appearing to read "Stuart F. Baum". The signature is fluid and cursive, with the first name "Stuart" and last name "Baum" clearly distinguishable.

Stuart F. Baum Ph.D.

Primary Examiner

Art Unit 1638

May 31, 2007

STUART F BAUM, PH.D.
PRIMARY EXAMINER